

REMARKS

Applicants acknowledge receipt of the Office Action mailed December 15, 2005.

In the Office Action, the Examiner (1) objected to claim 59; (2) rejected claims 33, 35, 36, and 60-62 under 35 U.S.C. § 103(a) as being unpatentable over *Castellano et al.* (U.S. Patent No. 5,728,074) in view of *Allen et al.* (U.S. Patent No. 5,837,546), *Buse et al.* (U.S. Patent No. 6,591,125), and *Tanabe et al.* (U.S. Patent No. 4,841,981); (3) rejected claims 37 and 38 under 35 U.S.C. § 103(a) as being unpatentable over *Castellano* in view of *Buse, Davies et al.* (U.S. Patent No. 6,733,655), and *Tanabe*; (4) rejected claim 58 under 35 U.S.C. § 103(a) as being unpatentable over *Castellano* in view of *Buse, Davies*, and *Tanabe*, and further in view of *White et al.* (U.S. Patent No. 5,438,271); (5) objected to claims 34 and 59 as being dependent upon a rejected base claim, but allowable if rewritten in independent form; and (6) allowed claims 25-32.

By this Amendment, Applicants amend claim 59 as suggested by the Examiner.

Before entry of this Amendment, claims 25-38 and 58-62 were pending in this application. After entry of this Amendment, claims 25-38 and 58-62 remain pending in this application. Of these claims, claims 25 and 33 are independent.

The originally-filed specification, claims, abstract, and drawings fully support the amendment to claim 59. No new matter has been introduced.

Applicants gratefully acknowledge the Examiner's allowance of claims 25-32.

In addition, Applicants acknowledge the Examiner's indication of allowable subject matter in claims 34 and 59. However, Applicants have not rewritten these claims to include all of the limitations of the base claim and any intervening claims because claim 33 is patentably distinguishable over the cited prior art.

Applicants respectfully traverse the Examiner's rejections for at least the reasons discussed below.

I. CLAIM OBJECTIONS

The Examiner's objection to claim 59 has been rendered moot in view of the amendment made to claim 59. Specifically, as suggested by the Examiner, Applicants have amended the dependency of claim 59 to depend from dependent claim 58. Applicants therefore request that the objection to claim 59 be withdrawn.

II. § 103(a) REJECTION OF CLAIMS 33, 35, 36, and 60-62

Claims 33, 35, 36, and 60-62 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Castellano*, in view of *Allen*, *Buse*, and *Tanabe*. Applicants respectfully traverse the rejection.

To establish a *prima facie* case of obviousness under 35 U.S.C. § 103(a), each of three requirements must be met. First, the reference or references, taken alone or combined, must teach or suggest each and every element recited in the claims. Second, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to combine the references in a manner resulting in the claimed invention. Third, a reasonable expectation of success must exist. Moreover, each of the three requirements must "be found in the prior art, and not be based on applicant's disclosure." See M.P.E.P. §2143, 8th ed., February 2003.

Castellano discloses a medical injection device, such as a pen-type injector 400, which includes a test strip 204 for holding a blood sample that is inserted into a test strip interface 206 to activate a blood characteristic monitor 202 and a microprocessor 32.

(*Castellano*, col. 14, ll. 38-40). The pen-type injector 400 enters a “sleep mode” to conserve power. (*Id.* at col. 20, line 67 - col. 21, line 2). However, as admitted by the Examiner, “*Castellano* is silent as to the details of the meter entering the active mode from the sleep mode and detecting the blood sample in the chamber and the current measurement.” (*Office Action*, p. 3, ll. 3-5).

To allegedly cure the deficiencies of *Castellano*, the Examiner relies on *Buse*, *Davies*, and *Tanabe*. The Examiner admits that “*Castellano*, as modified by *Buse* and *Davies* teaches a test strip having a working electrode and two counter electrodes, wherein a working electrode and one of the counter electrodes are used as the pair of fill-detect electrode[s], rather than providing a separate pair of fill-detect electrodes.” (*Id.* at p. 4, ll. 11-14). Accordingly, the Examiner relies on *Tanabe* and alleges that “*Tanabe* shows that a medical device may equally provide either a single element to perform two functions or separate elements to perform each of the two functions (col. 8, lines 13-27 of *Tanabe*).” (*Id.* at p. 4, ll. 14-16).

Applicants first submit that the Examiner improperly relies on *Tanabe* because *Tanabe* is non-analogous art. “In order to rely on a reference as a basis for rejection of an applicant’s invention, the reference must either be in the field of applicant’s endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned.” *In re Oetiker*, 977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992); M.P.E.P. § 2141.01(a). The present invention is generally directed to a system for measuring a glucose level in a blood sample using a test strip and a meter, while *Tanabe* discloses a catheter introduced into the pulmonary artery for use in measuring cardiac output or blood flow velocity. (*Tanabe*, Abstract). *Tanabe* is not “in the field of

applicant's endeavor," as the catheter is an invasive, intravenous device, as opposed to Applicants' non-invasive, non-intravenous blood glucose monitor and test strip. Moreover, the present invention addresses the problems of accurately measuring blood glucose levels conveniently and reliably using at least four electrodes that measure at least one electrical characteristic of a blood sample in a sample chamber of a test strip. (*Specification*, p. 3, ll. 4-11). In contrast, the section of *Tanabe* relied upon by the Examiner relates to "a catheter-type sensor 150 [which] incorporates [a] self-heating thermistor 1[, which is adapted to sense its own temperature] and...[a] thermistor 2, which serves as a temperature-sensitive element for sensing the temperature of blood within the pulmonary artery." (*Tanabe*, col. 8, ll. 13-19). Accordingly, *Tanabe* is not "reasonably pertinent to the particular problem with which the inventor was concerned." Therefore, *Tanabe* is non-analogous art and the rejection under 35 U.S.C. § 103(a) is improper.

Additionally, even if *Tanabe* is considered to be analogous art, which Applicants' do not necessarily concede, the Examiner has improperly characterized *Tanabe* as showing "a medical device [that] may equally provide either a single element to perform two functions or separate elements to perform each of the two functions." (*Office Action*, p. 4, ll. 14-16). *Tanabe* discloses a catheter-type sensor 150 that incorporates a self-heating thermistor 1 and a thermistor 2. (*Tanabe*, col. 8, ll. 13-14). Thermistor 1 is adapted to sense its own temperature, while thermistor 2 serves as a temperature-sensitive element for sensing the temperature of blood within the pulmonary artery. (*Id.* at col. 8, ll. 13-16). *Tanabe* fails to teach or suggest that either thermistor 1 or thermistor 2 can individually perform two functions, i.e., sensing the thermistor's own

temperature and sensing the temperature of blood within the pulmonary artery (emphases added). Accordingly, *Tanabe* fails to cure the deficiencies of *Castellano*, as modified by *Buse* and *Davies*.

As disclosed in the present specification, the working and counter electrodes 22 and 24 serve a function different and independent from that of fill-detect electrodes 28 and 30 (emphasis added). A first validation voltage is applied between the working and counter electrodes 22 and 24 to determine whether a blood sample is present in the sample chamber 88. Once the current between the working and counter electrodes 22 and 24 reaches a predetermined threshold value, the meter disconnects working and counter electrodes 22 and 24 and starts a fill timer. As soon as meter 200 starts the fill timer running, meter 200 applies a second validation voltage between the fill-detect electrodes 28 and 30 and measures the current flowing therefrom to determine whether sufficient blood sample has reached fill-detect electrodes 28 and 30 and whether the sample has become mixed with the chemical constituents in reagent layer 90. (*Specification*, p. 28, line 21 – p. 29, line 21). Thus, the working and counter electrodes 22 and 24 and the fill-detect electrodes 28 and 30 separately provide indications and validations to the meter as to the status of blood glucose measurement, with both sets of electrodes being equally important in obtaining an accurate test result (emphasis added).

Accordingly, with respect to independent claim 33, *Castellano*, in view of *Allen*, *Buse*, and *Tanabe* fails to teach or suggest the claimed combination, including, *inter alia*:

“[A] method of using a test strip to test a blood sample, said test strip including a sample chamber, a working electrode, a

counter electrode, a pair of fill-detect electrodes, and an auto-on conductor".

The Examiner has therefore not met at least one of the essential criteria for establishing a *prima facie* case of obviousness, wherein "the prior art reference (or references when combined) must teach or suggest all the claim limitations." See M.P.E.P. §§ 2142, 2143, and 2143.03. Accordingly, independent claim 33 is patentable over *Castellano*, *Allen*, *Buse*, and *Tanabe*. Applicants therefore respectfully request that the rejection of claim 33 under 35 U.S.C. § 103(a) be withdrawn and claim 33 be allowed.

Claims 34-38 and 58-62 depend from claim 33. As explained above, claim 33 is distinguished from *Castellano*, in view of *Allen*, *Buse*, and *Tanabe*, whether taken alone or in combination. Accordingly, claims 34-38 and 58-62 are also distinguished from *Castellano*, *Allen*, *Buse*, and *Tanabe*, for at least the same reasons as claim 33. Applicants respectfully request that claims 34-38 and 58-62 be allowed along with independent claim 33.

III. CONCLUSION

Applicants respectfully submit that independent claims 25 and 33 are in condition for allowance. In addition, claims 26-32, 34-38, and 58-62 are in condition for allowance at least due to their dependency from claims 25 and 33, respectively.

The Office Action contains characterizations of the claims and the related art with which Applicants do not necessarily agree. Unless expressly noted otherwise, Applicants decline to subscribe to any statement or characterization in the Office Action.

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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